Aktiivsed implanteeritavad meditsiiniseadmed. Osa 1: Üldised ohutusnõuded, tootja antav märgistus ja informatsioon

Active implantable medical devices - Part 1: General requirements for safety, marking and information to be provided by the manufacturer

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN 45502-1:2000 sisaldab Euroopa standardi EN 45502-1:1997 ingliskeelset teksti.	This Estonian standard EVS-EN 45502-1:2000 consists of the English text of the European standard EN 45502-1:1997.
Standard on kinnitatud Eesti Standardikeskuse 06.03.2000 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.	This standard is ratified with the order of Estonian Centre for Standardisation dated 06.03.2000 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation.
Euroopa standardimisorganisatsioonide poolt rahvuslikele liikmetele Euroopa standardi teksti kättesaadavaks tegemise kuupäev on 27.08.1997.	Date of Availability of the European standard text 27.08.1997.
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ICS 11.040.01

Võtmesõnad: informatsioon, kaitse, kirurgilised implantaadid, meditsiinivarustus, märgistus, ohutusnõuded, spetsifikaadid, steriilsus, tehnilised märkused, testid, õnnetuste ennetamine

EUROPEAN STANDARD

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EN 45502-1

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English version

Active implantable medical devices Part 1: General requirements for safety, marking and information to be provided by the manufacturer

Dispositifs médicaux implantables actifs
Partie 1: Règles générales de sécurité, marquage et informations fournies par le fabricant

Aktive implantierbare medizinische Produkte
Teil 1: Allgemeine Festlegungen für die Sicherheit, Aufschriften und vom Hersteller zur Verfügung zu stellende Informationen

This European Standard was approved by CENELEC on 1997-03-11 and by CEN on 1997-03-14. CEN and CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN/CENELEC Central Secretariat or to any CEN/CENELEC member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN/CENELEC member into its own language and notified to the CEN/CENELEC Central Secretariat has the same status as the official versions.

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Central Secretariat: rue de Stassart 35, B - 1050 Brussels

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Foreword

This European Standard has been prepared by the CEN/CENELEC Joint Working Group on Active Implantable Medical Devices (CEN/CLC JWG AIMD). Members of the Joint Working Group were nominated by one of the members of either CEN or CENELEC.

The text of the draft was submitted to the formal vote and was approved as EN 45502-1 by CENELEC on 1997-03-11 and by CEN on 1997-03-14.

This European Standard has been prepared under a mandate given to CEN and CENELEC by the Commission of the European Communities and the European Free Trade Association, and supports essential requirements of Directive 90/385/EEC.

Although both this Standard and the Directive deal with the same range of products, the structure and purpose of the two documents are different. Annex A of this European Standard correlates the requirements of the Directive with the subclauses of this Standard. Annex B provides references in the other direction, from this European Standard to the Directive. Annex C is a Rationale, providing some further explanation of particular subclauses of this European Standard. All three annexes are informative.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by 1998-03-01, and conflicting national standards shall be withdrawn at the latest by 1998-03-01.

Introduction

This standard specifies general requirements for ACTIVE IMPLANTABLE MEDICAL DEVICES, to provide basic assurance of safety for both patients and users.

To minimize the likelihood of a device being misused, this standard also details comprehensive requirements for MARKINGS and for other information to be supplied as part of the documentation with any ACTIVE IMPLANTABLE MEDICAL DEVICE.

For particular types of ACTIVE IMPLANTABLE MEDICAL DEVICE, the general requirements are supplemented or modified by the requirements of particular standards which are in preparation† as separate Parts of EN 45502. A requirement of such a particular standard takes priority over the corresponding requirement of this general standard. Where particular standards exist, this general standard should not be used alone. Special care is required when applying this general standard alone to ACTIVE IMPLANTABLE MEDICAL DEVICES for which no particular standard has yet been published.

1 Scope

This Part 1 of EN 45502 specifies requirements that are generally applicable to ACTIVE IMPLANTABLE MEDICAL DEVICES. For particular types of ACTIVE IMPLANTABLE MEDICAL DEVICES, these essential requirements are supplemented or modified by the requirements of particular standards which form additional parts of this European Standard.

The tests that are specified in EN 45502 are type tests and are to be carried out on samples of a device to show compliance.

This Part of EN 45502 is applicable not only to ACTIVE IMPLANTABLE MEDICAL DEVICES that are electrically powered but also to those powered by other energy sources (for example by gas pressure or by springs).

This Part of EN 45502 is also applicable to some non-implantable parts and accessories of the devices (see note 1).

NOTE 1 The device that is commonly referred to as an ACTIVE IMPLANTABLE MEDICAL DEVICE may in fact be a single device, a combination of devices, or a combination of a device or devices and one or more accessories. Not all of these parts are required to be either partially or totally implantable, but there is a need to specify some requirements of non-implantable parts and accessories if they could affect the safety or performance of the implantable device.

NOTE 2 The terminology used in this European Standard is intended to be consistent with the terminology of Directive 90/385/EEC.

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† At present (July 1997) particular standards for implantable cardiac pulse generators, implantable cardiac defibrillators, implantable infusion pumps, implantable neurostimulators, and cochlear implants are in preparation.

NOTE 3 In this European Standard, terms printed in SMALL CAPITAL LETTERS are used as defined in clause 3. Where a defined term is used as a qualifier in another term, it is not printed in small capital letters unless the concept thus qualified is also defined.

2 Normative references

This European Standard incorporates by dated or undated reference provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies.

EN 540	1993	Clinical investigation of medical devices for human subjects
EN 556	1994	Sterilization of medical devices - Requirements for medical devices to be labelled 'sterile'
EN 868-1	1997	Packaging materials for sterilization of wrapped goods Part 1: General requirements and requirements for the validation of packaging for terminally-sterilized devices.
EN 980	1996	Terminology, symbols and information provided with medical devices - Graphical symbols for use in the labelling of medical devices
EN 60068-2-32	1993	Environmental testing Part 2: Tests - Test Ed: Free fall (IEC 60068-2-32:1975 + A2:1990)
EN 60068-2-47	1993	Environmental testing Part 2: Tests Mounting of components, equipment and other articles for dynamic tests including shock (Ea), bump (Eb), vibration (Fc and Fd) and steady state acceleration (Ga) and guidance (IEC 68-2-47:1982)
EN 60601-1	1990	Medical electrical equipment Part 1: General requirements for safety (IEC 601-1:1988)
EN 60601-1-1	1993	Medical electrical equipment Part 1: General requirements for safety 1. Collateral Standard: Safety requirements for medical electrical systems (IEC 601-1-1:1992)
EN 60601-1-2	1993	Medical electrical equipment Part 1: General requirements for safety 2. Collateral standard: Electromagnetic compatibility - Requirements and tests (IEC 601-1-2:1992)

EN 60601-1-4	1996	Medical electrical equipment Part 1: General requirements for safety 4. Collateral standard: "Programmable electrical medical systems (IEC 601-1-4:1996)
EN 60601-2-27	1994	Medical electrical equipment Part 2: Particular requirements for the safety of electrocardiographic monitoring equipment (IEC 601-2-27:1994)
EN 60801-2	1993	Electromagnetic compatibility for industrial process measurement and control equipment Part 2: Electrostatic discharge requirements (IEC 801-2:1991)
HD 323.2.14	1987	Environmental testing Part 2: Tests - Test N: Change of temperature (IEC 68-2-14:1984 + A1:1986)
HD 323.2.36	1988	Environmental testing Part 2: Tests - Test Fdb: Random vibration wide band - Reproducibility medium (IEC 68-2-36:1973 + A1:1983)
ISO 8601	1988	Data elements and interchange formats - Information interchange - Representation of dates and times

3 Definitions

For the purposes of this Part of EN 45502, the following definitions apply.

3.1 medical device: An article, whether used alone or in combination, together with any accessories or software for its proper functioning, intended by the manufacturer to be used for human beings in the:

- diagnosis, prevention, monitoring, treatment or alleviation of disease or injury;
- investigation, replacement or modification of the anatomy or of a physiological process;
- control of conception

and which does not achieve its principal intended action by pharmacological, chemical, immunological or metabolic means but which may be assisted in its function by such means.

3.2 active medical device: A MEDICAL DEVICE relying for its functioning on a source of electrical energy or any source of power other than that directly generated by the human body or gravity.

3.3 active implantable medical device: An ACTIVE MEDICAL DEVICE which is intended to be totally or partially introduced, surgically or medically, into the human body or by medical intervention into a natural orifice, and which is intended to remain after the procedure.